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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,996	03/17/2004	Michael M. Meguid	RFSUNY-3673 R1410	4408

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Sander Rabin  
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Troy, NY 12180-4417

EXAMINER
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HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/802,996

Applicant(s)

MEGUID, MICHAEL M.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Applicant filed a response to the Non-Final Rejection of July 27, 2006, on October 24, 2006. Claims 3, 6, 9-23 are cancelled.

Claims 1, 2, 4, 5, 7, 8 are under consideration.

Applicant has filed amended claims on October 24, 2006. Applicant has cancelled claims and left the text of cancelled claims intact. Applicant also has left markings in claims that are not currently amended. This is not in compliance with MPEP 714 and 37 CFR 1.121(c). Applicant must comply with the rules set forth in the MPEP or risk not having amendments entered. In the interest of expediting prosecution, an action of the merits has been carried out as follows.

### **Withdrawn Rejections**

#### **35 U.S.C. § 112, 2<sup>nd</sup> parag.**

Applicant's arguments, see page 20 of Applicant's response, filed October 24, 2006, with respect to the rejection of claims 1-8 for being indefinite with regard to the use of the word, "substantially," have been fully considered and are persuasive. Applicant indicates that "substantially" has been deleted from claim 1. The rejection of claims 1, 2, 4, 5, 7, 8 has been withdrawn. It is noted that claims 3 and 6 are cancelled and thus, the rejection as it applies to these claims are withdrawn.

### **New/Maintained Rejections/Objection**

#### ***Specification***

The amendment filed October 24, 2006 is newly objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. The Examiner refers to the page numbers used in the submission of the amendment, October 24, 2006. Appendix B, "Marked Up" Version of Substitute Specification runs from pages 51 to 78.

Page 61, 1<sup>st</sup> parag., lines 4-5, is objected to because the deletion of "transgenic, cloned, or," and "engineered" and the addition of "modified," narrows the scope of the animals envisioned in the claimed invention.

Pages 62-63, are objected to for the insertion of publications. These publications were not part of the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 7, 8 remain rejected in modified form under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

1) a surgically modified wild-type non-human mammal, comprising a preoperative weight and a preoperative endogenous ghrelin production and gastrointestinal tract that

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has undergone a surgical modification, wherein said modification reduces the volume of a stomach of said gastrointestinal tract leaving a residual gastric pouch that food enters and in which food is lodged while undergoing digestion, and reduces the digestive area of said gastrointestinal tract; and wherein postoperatively, said surgically modified non-human mammalian animal exhibits a permanent reduction of said preoperative weight and a permanent reduction in said preoperative weight and a permanent reduction in said preoperative endogenous ghrelin production,

2) a surgically modified Zucker rat, comprising comprising a preoperative weight and a preoperative endogenous ghrelin production and gastrointestinal tract that has undergone a surgical modification, wherein said modification reduces the volume of a stomach of said gastrointestinal tract leaving a residual gastric pouch that food enters and in which food is lodged while undergoing digestion, and reduces the digestive area of said gastrointestinal tract; and wherein postoperatively, said surgically modified non-human mammalian animal exhibits a permanent reduction of said preoperative weight and a permanent reduction in said preoperative weight and a permanent reduction in said preoperative endogenous ghrelin production,

does not reasonably provide enablement for

1) surgically modified non-human mammals that are already existing murine, ovine, porcine, caprine, canine, feline, and other non-human mammals that comprise a naturally occurring mutation that results in obesity.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

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commensurate in scope with these claims for reasons of record, January 11, 2006, July 27, 2006.

Applicant's arguments filed October 24, 2006 have been fully considered and they are persuasive in part.

With regard to the enablement of a broad scope of genetically modified nonhuman mammals encompassed in claim 5, Applicant has indicated that the specification has been amended to provide examples in the art of other nonhuman mammals that comprise a naturally occurring genetic mutation related to obesity and exhibit obesity (Applicant's response, page 19). In response, Applicant is reminded that the insertion of these cited publications into the text of the specification is new matter. The Examiner cannot consider the publications and determine if they provide support for the claimed invention because copies have not been provided. Should Applicant wish to have these publications considered and be made of record, the publications must be listed on an IDS and copies of them must be provided. Thus, the rejection as it applies to this issue remains.

Applicant has indicated that claim 3, drawn to already existing transgenic nonhuman mammals and claim 6, drawn to already existing cloned nonhuman mammals are cancelled (Applicant's response, page 19). Because these claims are cancelled, the issues regarding these claims are withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is drawn to the use of "genetically modified" non-human mammals. In looking at the specification for guidance of the term "genetically modified," the now amended specification implies that "genetically modified" encompasses knockout and animals that comprise an overexpression transgene construct, and that "genetically modified" animals are contrasted from animals that have a naturally occurring mutation (specification, amended October 24, 2006, page 61, 1<sup>st</sup> parag.). However, in providing examples of "genetically modified" animals, the now amended specification describes mice and cows with naturally occurring mutations that exhibit an obese phenotype (specification, amended October 24, 2006, pages 62-63). As such, it is not entirely clear what types of animals are being claimed in claim 5.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8 remain rejected under 35 U.S.C. 102(b) as being rejected by Young et al., 1984, The American Journal of Clinical Nutrition, 40: 293-302, previously cited, for reasons of record, March 14, 2005, January 11, 2006, July 27, 2006.

Applicant's arguments filed October 24, 2006 have been fully considered but they are not persuasive.

Applicant indicates that during the telephone conference of August 31, 2006, it was discussed that the surgeries encompassed by claim 8 to create the nonhuman mammalian animal model encompassed by claim 1 left a patently distinct residual gastric pouch that food enters and in which food is lodged while undergoing digestion, the existence or presence of which was neither expressly nor inherently taught in Young et al. (Applicant's response, page 21, under "Remarks Responsive to 35 U.S.C. § 102(b) Rejections"). In response, Applicant's argument is not persuasive because Young et al. do teach that a gastric pouch was made in the Group 1 set of rats. Note that Young et al. teach that staples were placed just distal to the white ridge in the muscular portion of the true stomach and that a Roux-en-Y reconstruction was made (Young et al., page 294, 1<sup>st</sup> col., 1<sup>st</sup> parag. under Methods, and Figure 1). Young et al.'s surgically altered stomach appears to be the same as that taught by the Applicant, see specification, Figures 2-3. The specification teaches that the stomach is closed off with staples (specification, page 12, staples correspond to numbers 42, 43, 44 on the diagram of Figure 3), and that a pouch (number 27 on the diagram of Figure 3) was created. The specification also teaches that Roux-en-Y was performed by attaching the distal end of portion the jejunum (number 37, Figure 2) to the anterior surface of the gastric fundus at site number 40, Figures 2-3. Thus, the rejection as it applies to this issue remains.



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It is noted that while it is unclear what is encompassed by the term, "genetically modified" (see also 112, 2<sup>nd</sup> parag. rejection), the rejection of claim 5 remains because "genetically modified" appears to encompass non-human mammals that are transgenic and non-human mammals that comprise naturally occurring mutations.

### ***Conclusion***

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

